

Appl. No. 10/695,195
Amdt. dated January 23, 2006
Reply to Office action of 10/24/2005

REMARKS

Claims 21-25 are pending. Claim 25 is withdrawn. Claims 22-24 are amended. Claims 26 and 27 are new. Support for new Claims 26 and 27 can be found, e.g., in previously filed Claims 22 and 23. In particular, support for "fusion protein" recited in Claim 26 is found, e.g., on page 31, lines 17-37, through page 32, lines 1-14. The Specification is amended to provide a more descriptive title and correct various typographical errors.

Applicants believe that no new matter is added by way of amendment.

I. Objections to the Specification.

The Examiner objected to the title and to typographical errors in the specification. Applicants have made the necessary corrections in the above amendments.

In view of the foregoing amendment, Applicants respectfully request withdrawal of the objections to the Specification.

II. Rejections of Claims 21-24 under 35 U.S.C. §101 and §112, First Paragraph.

The Examiner rejected Claims 21-24 under 35 U.S.C. §101 and §112, first paragraph, on the basis that the claimed invention is not supported by a credible, specific, or substantial asserted utility. The Examiner alleges Applicants' assertion that the polypeptides of the present invention have biological activities similar to known IL-1 family members cannot be accepted in the absence of supporting evidence. Applicants are only required to provide evidence if, when considered as a whole, leads the skilled artisan to conclude that the asserted utility is more likely than not true (see, e.g., M.P.E.P section 2107.03).

The specification states that the molecule of the present invention, IL-1 ζ , has "... substantial likelihood of synergy with other IL-1 or IL-12 antagonists or agonists." (see, e.g., page 21, lines 27-28, of the specification). Furthermore, Applicants have stated in the specification, that IL-1 ζ is likely to have IL-12 promoting activities similar to IL-1 γ , in particular tumor activity (see, e.g., page 69, line 33 through page 70, line 2).

In support of this asserted utility, Applicants submit Gao, et al. (2003) J. Immunol. 170:107-113 ("Gao"). The Gao references teaches that IL-1H4/IL-1F7 (a.k.a.

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IL-1 ζ) adenoviral mediated gene transfer of IL-1H4 to induce an IL-12- and Fas ligand dependent anti-tumor response. Gao further teaches that administration of this IL-1 ζ adenoviral construct to mice lacking the IL-12p40 subunit of IL-12, failed to confer any anti-tumor activity. Thus, the authors conclude that "... IL-1H4 may promote the development of the anti-tumor response through enhanced IL-12 production" (see, Gao, et al., supra, page 110, column 2).

Applicants submit that the asserted utility of IL-1 ζ synergizing and promoting IL-12 type immunity is supported by the foregoing reference. For the Examiner's convenience, Gao and a GenBank printout of the sequence of IL-1H4 are provided along with a supplemental IDS. Applicants therefore believe that a skilled artisan would more likely than not believe that the polypeptides of the present invention are supported by a substantial, specific, and credible utility. With regard to the 35 U.S.C. 112, first paragraph rejection, Applicants submit that because the present invention is, in fact, supported by a substantial, specific, and credible utility. Thus, the skilled artisan would know how to make and use the polypeptides of the present invention.

In view of the forgoing, Applicants submit that the rejection of Claims 21-24 under 35 U.S.C. §101 and §112, first paragraph, is overcome, and new Claims 26 and 27 are free from this rejection. Withdrawal of this rejection is respectfully requested.

IV. Rejections of Claims 22-24 under 35 U.S.C. §112, Second Paragraph.

The Examiner rejected Claims 22-24 under 35 U.S.C. §112, second paragraph. In particular, Claim 22 was rejected for reciting "a glycosylation or phosphorylation". As amended, Claim 22, no longer recites the foregoing.

Claim 23 was rejected for use of "including". As amended, this claim no longer recites "including".

Claim 24 was rejected for the use of "and/or". As suggested by the Examiner, Claim 24 is amended to recite "and".

In view of the forgoing, Applicants believe that the rejection of Claims 22-24 under 35 U.S.C. §112, second paragraph, is overcome, and new Claims 26 and 27 are free from this rejection. Withdrawal of this rejection is respectfully requested.

Appl. No. 10/695,195
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Conclusion

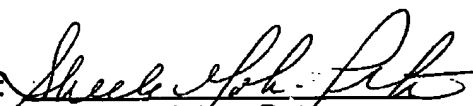
Applicants' current response is believed to be a complete reply to all the outstanding issues of the latest Office action. Further, the present response is a bona fide effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicants respectfully request reconsideration and passage of the amended claims to allowance at the earliest possible convenience.

Applicant believes that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

Date: January 23, 2006

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